

§ 890.3420

respect to general requirements concerning records, and §820.198, with respect to complaint files.

§ 890.3420 External limb prosthetic component.

(a) *Identification.* An external limb prosthetic component is a device intended for medical purposes that, when put together with other appropriate components, constitutes a total prosthesis. Examples of external limb prosthetic components include the following: Ankle, foot, hip, knee, and socket components; mechanical or powered hand, hook, wrist unit, elbow joint, and shoulder joint components; and cable and prosthesis suction valves.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807. The device also is exempt from the current good manufacturing practice regulations in part 820, with the exception of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.

§ 890.3475 Limb orthosis.

(a) *Identification.* A limb orthosis (brace) is a device intended for medical purposes that is worn on the upper or lower extremities to support, to correct, or to prevent deformities or to align body structures for functional improvement. Examples of limb orthoses include the following: A whole limb and joint brace, a hand splint, an elastic stocking, a knee cage, and a corrective shoe.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807. The device also is exempt from the current good manufacturing practice regulations in part 820, with the exception of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.

§ 890.3490 Truncal orthosis.

(a) *Identification.* A truncal orthosis is a device intended for medical purposes to support or to immobilize fractures, strains, or sprains of the neck or trunk of the body. Examples of truncal

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orthoses are the following: Abdominal, cervical, cervical-thoracic, lumbar, lumbo-sacral, rib fracture, sacroiliac, and thoracic orthoses and clavicle splints.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807. The device also is exempt from the current good manufacturing practice regulations in part 820, with the exception of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.

§ 890.3500 External assembled lower limb prosthesis.

(a) *Identification.* An external assembled lower limb prosthesis is a device that is intended for medical purposes and is a preassembled external artificial limb for the lower extremity. Examples of external assembled lower limb prostheses are the following: Knee/shank/ankle/foot assembly and thigh/knee/shank/ankle/foot assembly.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 63 FR 59231, Nov. 3, 1998]

§ 890.3520 Plinth.

(a) *Identification.* A plinth is a flat, padded board with legs that is intended for medical purposes. A patient is placed on the device for treatment or examination.

(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedure in subpart E of part 807. The device is also exempt from the current good manufacturing practice regulations in part 820, with the exception of §820.180, with respect to general requirements concerning records and §820.198 with respect to complaint files.

§ 890.3610 Rigid pneumatic structure orthosis.

(a) *Identification.* A rigid pneumatic structure orthosis is a device intended for medical purposes to provide whole body support by means of a pressurized suit to help thoracic paraplegics walk.